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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/589,082

09/05/2006

Ulrich Kautz

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34375 7590 12/23/2008

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Alexandria, VA 22314

EXAMINER

O'DELL, DAVID K

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/589,082 | Applicant(s) KAUTZ, ULRICH | |
| | Examiner David K. O'Dell | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-11, 13-14 are pending.

Priority

2. This application is a 371 of PCT/EP05/50708 filed 02/17/2005, which claims priority to EUROPEAN PATENT OFFICE (EPO) 04003592.5 filed 02/18/2004.

Claim Rejections/Objections Withdrawn

3. The rejections of claims 1-11 under 103(a) as being obvious over U.S. 7,329,676 in view of US Pre-Grant Publication US 2006/0116518 is withdrawn since these documents have been eliminated as prior art in a 103(a) rejection via the 103(c) exception .

Claim Rejections/Objections Maintained/ New Grounds of Rejection

4. The rejection of claims 1-11 under the judicially created doctrine of non-statutory obviousness type double patenting is maintained. Applicant's representative has argued that no motivation is present in the 103(a) rejection, which is incorrect, the examiner stated previously "One of ordinary skill would be motivated to make the compounds of the invention because he would expect the compounds to have similar properties, indeed we see that these compounds are both potent inhibitors of PDE4." It is not necessary that the skilled artisan be motivated to be motivated, but that he would be so motivated without a motivation to his motivation. The expectation of making further active compounds that may be used as drugs is a motivation, since such drugs may be used to treat illnesses in humans and other animals. The applicants' representative appears to require a motivation for the motivation to do this. The motivation that motivates the motivation may be a desire to help humanity, money, fame, or power. The

motivation of the motivation is the subject of philosophy and psychology and is not an issue here.

No comment has been made on the numerous copending applications, 10/524820, 10/589082, 10/590803, 10/590805, 10/591472, 10/591478, 10/591480, 10/591768, 11/661369, 11/661377, 11/795981, 11/884934, 11/884935, 11/885425, 12/000710, and how they relate to the instant claims. The applicants' representative has stated that no "better" rejections could be made. It is respectfully submitted that the relationship of one double patenting rejection to another as "better" has no effect on the propriety of such rejections. The examiner would like to know which of the above applications has a species that would read on the instant claims, or an application that has a generic claim that encompasses the instant claims, or claims that overlap in scope. If there are patentable differences the examiner would like the applicant to make them of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

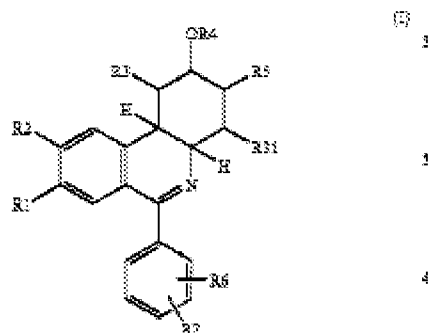
with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. patent 7,329,676 in view of US Pre-Grant Publication US 2006/0116518. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- A) Determining the scope and contents of the prior art.
- B) Ascertaining the differences between the prior art and the claims at issue.
- C) Resolving the level of ordinary skill in the pertinent art.
- D) Considering objective evidence present in the application indicating obviousness or nonobviousness.

A) Determining the scope and contents of the prior art: U.S. 7,329,676 teaches a genus of compounds shown below, in particular the '676 definitions of R4 where both H, and alkylcarbonyl are listed as part of the genus:



R1 is hydroxy, 1-4C-alkoxy, 3-7C-cycloalkoxy, 3-7C-cycloalkylmethoxy, or completely or predominantly fluorine-substituted 1-4C-alkoxy.

or in which

R1 and R2 together are a 1-2C-alkylenedioxy group.

R3 is hydrogen or 1-4C-alkyl.

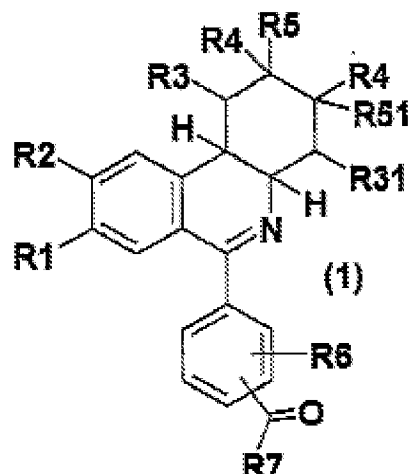
R31 is hydrogen or 1-4C-alkyl,

R4 is hydrogen, 1-4C-alkyl, completely or predominantly fluorine-substituted 1-4C-alkyl, 1-4C-alkoxy-1-4C-alkyl, hydroxy-2-4C-alkyl or 1-7C-alkylcarbonyl.

RS is hydrogen or 1-4C-alkyl.

R⁶ is hydrogen, 1-4C-alkyl, trifluoromethyl, 1-4C-alkoxy, completely or predominantly fluorine-substituted 1-4C-alkoxy, 3-7C-cycloalkoxy, 3-7C-cycloalkylmethoxy, halogen, nitro, cyano, hydroxyl, 1-4C-alkylcarbonyloxy, amino, mono- or di-1-4C-alkylamino, phenyl, phenyl-1-4C-alkyl, 1-4C-alkylcarbonylamino, phenoxy or C(O)OR⁶1, wherein

US Pre-Grant Publication US 2006/0116518 teaches a genus of compounds bearing the guanidiny1 moieties at R7, but differ in the identity of the R4 or R5 group. A relevant portion is shown below:



in which

R1 is hydroxyl, 1-4C-alkoxy, 3-7C-cycloalkoxy, 3-7C-cycloalkylmethoxy or completely or predominantly fluorine-substituted 1-4C-alkoxy, and

R2 is hydroxyl, 1-4C-alkoxy, 3-7C-cycloalkoxy, 3-7C-cycloalkylmethoxy or completely or predominantly fluorine-substituted 1-4C-alkoxy,

R1 and R2 together are a 1-2C-alkylenedioxy group,

R3 is hydrogen or 1-4C-alkyl,

R31 is hydrogen or 1-4C-alkyl,

or in which

R3 and R31 together are a 1-4C-alkylene group,

R4 is hydrogen or 1-4C-alkyl,

R5 is hydrogen,

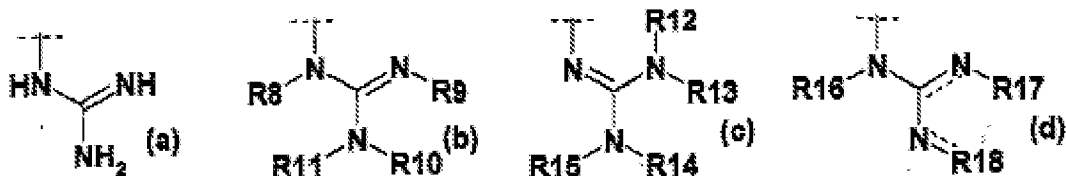
R51 is hydrogen,

or in which

R5 and R51 together represent an additional bond,

R6 is hydrogen, halogen, nitro, 1-4C-alkyl, trifluoromethyl or 1-4C-alkoxy,

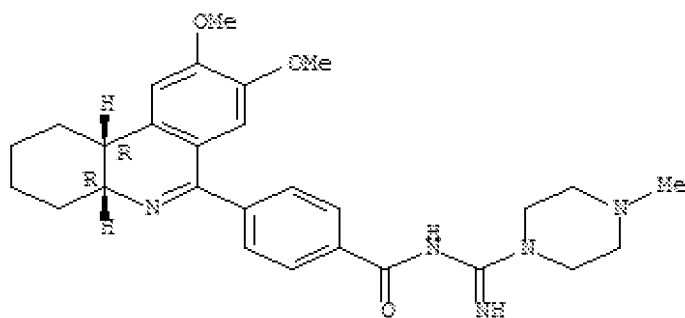
R7 is a radical of formulae (a), (b), (c) or (d)



A specific compound which bears the piperazinyl moiety of the instantly elected species is shown below:

RN 667422-59-5 CAPLUS
CN Benzamide, 4-[(4aR,10bR)-1,2,3,4,4a,10b-hexahydro-8,9-dimethoxy-6-phenanthridinyl]-N-[imino(4-methyl-1-piperazinyl)methyl]- (CA INDEX NAME)

Absolute stereochemistry.



B) Ascertaining the differences between the prior art and the claims at issue.

The instant claims are drawn to compounds that differ from the US Pre-Grant Publication US 2006/0116518 by the definition of R₄, and U.S. 7,329,676 teaches very similar compounds that have this alkoxycarbonyl or hydroxy modification. In the alternative, the instantly claimed compounds may be seen as variants of the '676 application which have the R⁷ modification as taught by US Pre-Grant Publication US 2006/0116518.

C) Resolving the level of ordinary skill in the pertinent art: The level of ordinary skill is high. Someone preparing these compounds would be trained in organic chemistry and would recognize the very close structural similarity and would expect them to have similar properties.

D) Considering objective evidence present in the application indicating obviousness or nonobviousness: The compounds of the claims at hand are analogs of old compounds. One of ordinary skill would be motivated to make the compounds of the invention because he would

expect the compounds to have similar properties, indeed we see that these compounds are both potent inhibitors of PDE4. *In re Grabiak* 226 USPQ 870, "[w]hen chemical compounds have "very close" structural similarities and similar utilities, without more a *prima facie* case may be made", *In re Deuel* 34 USPQ2d 1210, "a known compound may suggest its **analogs** or isomers, either geometric isomers (*cis v. trans*) or position isomers (emphasis added) (*e.g. ortho v. para*)".

6. Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/524,634 in view of US Patent 7,329,676 . A detailed discussion of this rejection can be found in the ODP rejection above which is founded in the same reasoning and documents.

This is a provisional obviousness-type double patenting rejection.

7. The examiner has also identified fifteen applications with the inventor in common, all with similar titles and subject matter: 10/524820, 10/589082, 10/590803, 10/590805, 10/591472, 10/591478, 10/591480, 10/591768, 11/661369, 11/661377, 11/795981, 11/884934, 11/884935, 11/885425, 12/000710. The burden is now shifted to the applicant to provide information regarding any instance of double patenting in view of the rejections above.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571)272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

/Rita J. Desai/
Primary Examiner, Art Unit 1625